NATIONAL CITIZENS INQUIRY

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EVIDENCE

(Translated from the French)

Witness 2: Hélène Banoun
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[00:00:00]

Konstantinos Merakos
So hello again. We've solved the little technical problem with the PowerPoint and now we'll continue with our next witness, Madame Hélène Banoun. Madame Hélène Banoun, can you hear us?

Hélène Banoun
Yes.

Konstantinos Merakos
Perfect. We have the PowerPoint here on the screen for people to see. I'm going to be the one manually changing the pages, so just let me know when; we're going to be working as a team on your PowerPoint.

I'm going to start by swearing you in. Do you solemnly swear or affirm to tell the truth, the whole truth, and nothing but the truth? Say "yes" or "I do."

Hélène Banoun
Yes, I swear, with the comment that when it comes to science, there's no such thing as truth. I can give the state of science that seems correct to me today. All this can change.

Konstantinos Merakos
Fine, but the answer is yes?

Hélène Banoun
Yes, of course.

Konstantinos Merakos
Excellent. So I'm going to ask you for your full name and to spell your last name, please.

Hélène Banoun
My family name is Banoun, B-A-N-O-U-N.

Konstantinos Merakos
And your complete name is. . .

Hélène Banoun
My first name is Hélène, H-É-L-È-N-E.

Konstantinos Merakos
Perfect. And where are you currently located?

Hélène Banoun
I'm in Marseille, in the south of France.

Konstantinos Merakos
Perfect, and are you alone in the room or with someone else?

Hélène Banoun
No, I'm alone in the room.

Konstantinos Merakos
Excellent. So Madame Banoun, I have your CV in front of me. I'd like to start by talking a little about your expertise. We'll start with this. Tell us a little about yourself.

Hélène Banoun
I'm a pharmacist-biologist. I was a researcher at Inserm, the French National Institute for Health and Medical Research, a very long time ago. I worked in anti-cancer molecular pharmacology and I started working intensively in virology a few years ago, and particularly since the pandemic. I've published bibliographical reviews in international journals, in particular a review on the evolution of the virus, and various scientific articles in international peer-reviewed journals. So I think I have some expertise as an independent scientist. That's what I can say.

Konstantinos Merakos
Excellent.

Hélène Banoun
I should add that I have been a member of the French Independent Scientific Council since its creation in April 2021.

Konstantinos Merakos
Excellent. So where do you currently work?

Hélène Banoun
I work from home since I'm retired. I'm an independent researcher, a volunteer.

Konstantinos Merakos
And in your CV, could we talk about at least one or two themes, namely the work in progress, an independent analysis in English?

Hélène Banoun
I work with Dr. Maria Gutschi, who presented her work to the National Citizens Inquiry in English a few days ago. There's also Dr. David Wiseman, David Asher. So we're working on the analysis of the European Medicines Agency's report on vaccines and on pre-clinical trials of RNA vaccines, among other things. I work in collaboration with these people. By the way, I'd like to thank Dr Maria Gutschi and David Wiseman for some of the things I'm going to say in my presentation.

Konstantinos Merakos
Excellent.

Hélène Banoun
I've also worked with Professor Patrick Provost at Laval University, and together we published an article on the necessary observation period for adverse effects of RNA vaccines.

Konstantinos Merakos
Perfect. Thank you very much. So without further ado, let's start with your PowerPoint. Is that okay with you?

Hélène Banoun
I'm not going to repeat what I've said about myself, so we'll move on to the second slide. I'm going to talk about the problem of regulating these RNA vaccines. Are they gene therapies or are they vaccines—or both, if possible? I'm just going to give a quick introduction to help you understand the problem, that is, the way these vaccines work. So on the first slide, I'll quickly remind you what a virus is. So it's a complete parasite made up of nucleic acid. You can see in the center of the diagram: everything in orange is nucleic acid. In this case, for coronaviruses, it's RNA. Then, in green, you have an envelope to which surface proteins are attached, including the famous spike protein, which is an antigen of the virus and which is very abundant, and which will therefore be recognized by the attacked organism, by the person who is ill, as an antigen.

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This person will produce antibodies against these antigens and some of these antibodies are capable of neutralizing the virus. That's why vaccine manufacturers have chosen the spike as the antigen for the vaccine.

On the next slide, I'm going to say a few words about the immune system. The immune system is divided into several branches. There is innate immunity, which is non-specific and has no memory of pathogens, and adaptive immunity, which is pathogen-specific and retains a memory via cells. This adaptive immunity is divided into two branches: cellular immunity, whose effectors are cells, in particular T-lymphocytes; and humoral immunity, whose effectors are antibody molecules produced by B-lymphocytes.

So I've got a little diagram here, where, on the bottom right, you can see the virus with these little spikes on the surface in red and the antibodies in pink-white that bind to them. But what needs to be explained is that all these systems cooperate with each other and cannot act alone. For example, the macrophages you see at the top right, the kind of purple cell, play a role in innate immunity, but also in adaptive immunity through cooperation with lymphocytes. In fact, we'll see that with conventional vaccines, and especially with RNA vaccines, we focus solely on antibodies and one virus antigen. That's a pretty limited mode of action.

On the next slide, we can see the different types of classic and new vaccines that we're accustomed to using. So historically, we've gone from live attenuated vaccines to RNA vaccines. In other words, the first vaccines were made with live attenuated viruses—in other words, empirically, as was the case for smallpox. They were attenuated using very empirical, very crude methods. Then we developed more refined methods. These were the first viruses.

We've also tried to make chemically inactivated viruses. We've tried to make particles that look like viruses. We've used virus vectors, such as DNA vaccines from AstraZeneca and Janssen. Historically, we have also used antigens. We chose an antigen, a part of the virus, and we made recombinant proteins, meaning that we synthesized, either chemically or by biological recombination, proteins that serve as antigens.

And then more recently of course we have DNA vaccines, in which the vaccinated individual synthesizes the antigen, and then, finally, the famous mRNA vaccines, in which the vaccinated individual is injected with part of the virus's genetic code and is expected to produce the antigen himself. And so we focus on a specific antigen and antibodies.

Regarding the next slide, I'd just like to make a brief comment about this WHO [World Health Organization] diagram, which tells us that only antibodies are represented: since the beginning of the history of vaccinology and immunology, only antibodies have been taken into account in the immune response. We see on this diagram that viruses are depicted and then these small kind of Y-shaped molecules are the antibodies that are supposed to bind to the virus and neutralize it. And particularly for coronaviruses, which are respiratory viruses with a nasal entry point, innate immunity is essential: the innate immunity found in the nose has little to do with antibodies, in fact. And so with this idea of focusing on the antibody response, we forget about the T-cell response, cellular immunity, and innate immunity. And that's a problem for vaccines.

So on the next slide, let me remind you of the same thing. In actuality, we've forgotten that the organism reacts to a living, whole pathogen, introduced via a natural pathway: in this

case, the upper respiratory tract in the case of a coronavirus. And here, with mRNA vaccines, we're going to inject only a genetic code into the muscle. So it has very little to do with the attack of a real, natural, living pathogen.

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For the next slide, I'd like to say a few words about the phenomenon of the facilitation of viral infections by antibodies, known in English as "antibody-dependent enhancement." This phenomenon contradicts the protective role of antibodies asserted by classical immunology, since immunology tells us that antibodies are there to protect us. But in fact, this phenomenon of facilitating viral infections has again recently been discussed in relation to the clinical aspect of COVID-19. Actually, in some cases, antibodies are harmful and, in fact, antibody levels are correlated with disease severity. So it's not necessarily a causal relationship, but it can't be easily ruled out.

Incidentally, I published a theoretical article on this subject in relation to the theory of evolution. You'll find the reference at the top of the slide. So antibody-dependent reinforcement of infection is the accepted mechanism to explain severe reinfections due to dengue virus—among others, because it happens with other viruses—and also the higher occurrence of severe dengue in vaccinated people. Vaccine antibodies are capable of aggravating an infection that subsequently occurs with a dengue virus similar to the one with which we vaccinated. And so this antibody effect seems to contradict the immunological theory. This is another criticism that can be levelled at these vaccines, which focus on the production of antibodies: more and more antibodies to fight the disease, when in fact they can sometimes work against a patient.

On the next slide, I'm going to quickly remind you of the principle behind the design and synthesis of these messenger RNA vaccines. So they comprise synthetic messenger RNA molecules which direct the production of the antigen that will provoke an immune response. You're injected with part of the genetic code of an antigen that you'll manufacture, and against which you'll produce an immune response in the form of antibodies. Now, I'm not going to go into detail about how this is done because it's very complicated. RNA is transcribed in vitro from a DNA matrix. This may explain the recent discovery that there is contaminating DNA in vaccine vials that shouldn't be there. There are also a number of stages in the manufacture of these messenger RNAs that are poorly handled because they are completely new; and above all, there have been many subcontractors in the manufacturing process to produce billions of doses, so we can expect problems with this manufacturing process. All this was detailed by Maria Gutschi in a previous presentation to the National Citizens Inquiry.

For the next slide, I've put together a diagram showing the theoretical mode of action of messenger RNA vaccines. Now, I'm not going to go into detail because it's very complicated, but I will remind you that the designers of these vaccines are only interested in the fate of these products in specialized immune cells, which are known as antigen-presenting cells, APC cells. But we now know that RNA circulates throughout the body and can be translated into this famous spike protein by numerous cell types. And we also know that this spike is toxic, not to mention the toxicity of nanoparticles, because messenger RNA is wrapped in nanoparticles that serve to protect it and act as vectors to deliver it to the site of action. So there you have it. The official site of action is immune cells but in reality, this RNA goes everywhere and is possibly translated into spike by different cell types in virtually every organ.

So on the next slide I've just taken a screenshot from Professor Frajese, who spoke at the International COVID Summit in Brussels last week, where he reminds us that these vaccines are, in fact, prodrugs; in other words, they are pharmacologically inactive in themselves. This is important to understand from a legal and scientific point of view, and even for politicians. They are pharmacologically inactive and must undergo metabolic transformation by the body to achieve their supposed activity. And so if you like, it's difficult to subject them to the regulation of conventional vaccines or conventional drugs; it's something completely new.

On the next slide, the same Professor Frajese reminded us that we don't know how this product works. We don't know where it is biodistributed or how it is excreted. And he also reminded us that we don't know on what scientific research the authorization of these RNA vaccines for pregnant women is based.

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So how are they supposed to work officially? On the next slide, I've taken a diagram from the Finnish Health Institute because I thought it was very educational, where they show the official mode of action of RNA vaccines, according to the official narrative. So the messenger RNA contains the genetic instruction to make the spike; it penetrates the muscle; the muscle cell produces this spike, which is recognized as foreign by the body, which protects itself against it by making antibodies. That's the official mode of action, but it's not so simple because on the next slide you'll see that, in fact, this messenger RNA contains the modified code of the virus' spike protein, which is itself modified.

So all this is not natural RNA and it's not the spike of the virus which circulated around the world. And let me remind you that almost all the pathogenic effects of the COVID-19 virus, SARS-CoV-2, are due to this toxicity of the spike, the surface protein. And moreover, the vaccine spike is apparently more toxic than the viral spike, precisely because it has been modified to be more stable.

On the next slide, we see that lipid nanoparticles, or LNPs, which act as vectors and protection for messenger RNA, penetrate the whole body and many cell types. And these nanoparticles are also toxic. This seems to be becoming clearer now. So we now know that the modified RNA of the vaccine and the modified spike of the vaccine produced by the vaccinated individual can persist for months in the body. I've also published—you'll find the reference on the bottom left—a summary of the bibliography on what was known before and since the anti-COVID RNA vaccines were marketed regarding the biodistribution and, possibly, excretion. But that's another matter, and we won't go into it here.

On the next slide, we see that transfected cells—meaning those in which the RNA has penetrated and been translated into spike proteins—well, these cells will express the protein on their surface. They will induce the synthesis of anti-spike protein antibodies. But they can also be destroyed because they will be recognized as foreign by the immune system, since they carry a foreign protein on their surface. This can explain the undesirable side effects as cells necessary to the proper functioning of the human body are destroyed.

And so on the next slide, we come to the heart of the matter. According to this principle of action, RNA vaccines are gene therapy products. In fact, according to the FDA [Food and Drug Administration]: "Gene therapy products are any products whose effects are mediated by," here I summarize, "the translation of genetic material," which happens—a

transfer—"and which are administered in the form of nucleic acids," which happens. So this corresponds exactly to the mode of action of gene therapy products.

The next slide shows the European Medicines Agency's definition of gene therapy products. A gene therapy product "contains an active substance consisting of a nucleic acid, with a view," in particular here, "to adding a genetic sequence," which is exactly the case. "Its effect, whether therapeutic or prophylactic," which is the case here, "is directly linked to the sequence of this nucleic acid" that is injected. This is exactly the case here. But what you need to know is that the European Medicines Agency was already telling us in 2009 that gene therapy medicinal products do not include vaccines against infectious diseases. So through a simple regulation, we decided that these products, which were objectively gene therapy products, would be excluded from the regulation of vaccines against infectious diseases. We'll look at the chronology of this exclusion in a moment.

I'll perhaps move on quickly over the next slides on vaccine clinical trials, because I don't want to take up too much time, so as to allow questions to be asked. It was just to remind you, chronologically speaking, that the sequence of the first official SARS-CoV-2 virus was officially published in January 2020 and that the complete genome was officially published on January 11, 2020. Despite this, it's worth noting that the first vaccine candidate entered human clinical trials with unprecedented speed on March 16.

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On the next slide, we'll look specifically at the Pfizer clinical trial. Development began on January 10, 2020, the day before the virus genome was fully published. And from what I've been able to understand by researching official documents, phase I on humans began before the phase on animals. Since the rat studies were approved on December 17, 2020, they would have started in June 2020, and they would have started after phase I on humans. So all these stories coincided, which explains why these products couldn't undergo the usual testing. In particular—again, from what I understand because maybe I'm wrong; it's not very clear in the documents—it seems that phases I, II and III were conducted simultaneously. And I will remind you that phase I is used to decide the optimal dose. In phase I, there were three dose levels, but if phase I is carried out at the same time as phase II and phase III, they won't be able to choose the optimal dose for phase III, which is the pre-commercialization phase. And this seems to have been what happened.

The next slide on the continuation of the Pfizer trial, is just to point out that a whistle-blower, Brook Jackson, had published an article in *The British Medical Journal* which reported integrity problems in the clinical trial data. So we need to look at this clinical trial with circumspection. There may have been problems. I wouldn't say fraud, but integrity problems.

Concerning the Moderna trial and again the chronology of this trial: Moderna officially began work on the vaccine on January 13, 2020. I remind you that the genome was published on January 11. But in fact, we later learned from a journal—you have the reference below—that Moderna had started trials as early as 2019, so before the official start of the pandemic. And in fact, these data were so encouraging that the CEO had announced in 2019 that the company would double its vaccine development program in 2020.

The next slide shows the continuation of the Moderna trial. Likewise, here we can say that the preclinical studies on non-human primates were conducted in collaboration with the American Institute of Health, and they published about monkeys in July 2020, while the

phase III on humans began on July 27, 2020. In other words, phases I and II—if they took place because I haven't found a reference to phase II—well, they began at the same time as, or perhaps even before, the animal studies. So there really is a problem with the clinical trials.

So for the next slide, I'm going to talk about the history of gene therapy regulation in relation to vaccine regulation. In 2005, the WHO granted nucleic acid-based vaccines—which, I remind you, is the case for RNA vaccines—the status of vaccines. They are vaccines. In 2007, the European Medicines Agency defined nucleic acids for prophylactic use—and vaccines fall within this framework—as GTPs, in other words, gene therapy products. Similarly, in 2007, the FDA defined DNA plasmid-based vaccines as gene therapy products. So at that time, there was no talk of RNA vaccines because they weren't yet a reality. We hadn't even imagined making them yet. And in 2008, the European Medicines Agency confirmed that DNA vaccines were subject to the regulations governing gene therapy products.

On the next slide: What happens in September 2009? Well, the European Medicines Agency decides that vaccines against infectious diseases cannot be classified as gene therapy products. Suddenly, they're no longer subject to regulations, and the same thing was decided by the FDA in 2013. The regulation of gene therapy products does not apply to infectious disease vaccines.

And we'll see on the next slide: what happened between 2008 and 2009? Since up until 2008, nucleic acid-based vaccines, including RNA vaccines, had to comply with these regulations? Well, in 2009-2010, we had the H1N1 flu pandemic and Dr. Anthony Fauci was looking for solutions for a universal flu vaccine.

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And in November 2010, talk began of a DNA vaccine, but not yet of an RNA vaccine. And in 2011, two European companies, CureVac and Sanofi, began collaborating with DARPA, the U.S. Army Research Agency, to develop RNA vaccines. And in 2013, DARPA awarded Moderna a grant of up to $25 million to develop a messenger RNA vaccine-based therapy against infectious diseases. So there seems to be a temporal concordance between this regulatory change and the decision by U.S. medical authorities to focus everything on RNA vaccine research against infectious diseases, but most specifically against influenza.

So just to let you know that all the references for everything I'm telling you here are in a preprint that I've uploaded to Qeios [since published and available as Exhibit QU-11 in the French and QU-11a in English]. It's really a preprint because I've modified it a lot. I'm going to modify it again in order to resubmit it to other journals because it's been rejected due to it being a very sensitive subject. I've been told that the regulation of RNAs is an important subject. All the people who criticized me told me it's very delicate. So in this preprint, I remind you of something very important: that RNA vaccines should follow the regulations for gene therapy products because objectively, they are gene therapy products. But what's important to note is that an RNA molecule, virtually the same molecule that targets tumors—that is, one used to combat cancer—is considered a gene therapy product. But as a vaccine against an infectious disease, it is no longer considered a gene therapy. And this exclusion is scientifically unjustified.

So on the next slide, I confirm the bizarre nature of this exclusion by the fact that Moderna and Pfizer expected their product to be subject to the regulation of gene therapy products. This came out in a press release from 2020, you have the references here for Moderna, and

from 2014 for Pfizer. So according to the CEO of BioNTech, who worked with Pfizer, they really expected messenger RNAs against infectious diseases to be considered gene therapy products. So even the manufacturers expected it. That's why they've produced trials that correspond in part to those for gene therapy products.

On the next slide, we see that whether RNA vaccines are considered vaccines or gene therapy products, they must in either case comply with the rules applicable to human medicinal products according to the European Medicines Agency. And so, as I said, if it's a cancer therapy or a vaccine, they won't undergo the same controls.

Now, it's worth noting that the European Medicines Agency requires additional studies for vaccines that use new formulations—and we'll see that not all these studies have been carried out. Vaccines in general have long been exempted from pharmacokinetic controls without any real scientific justification. Why exempt products that are administered to the entire human population, as opposed to drugs that are only administered to a few patients? But it should be noted that, as RNA vaccines represent a new class of drugs, they should rightly be subject to more controls than conventional vaccines because they are based on new technologies.

In fact, the European Medicines Agency wrote, before the arrival of RNA vaccines of course: "Vaccines are in most cases administered to a large number of healthy individuals. A robust non-clinical safety evaluation is required." So there you have it. It's a real problem, as the European Medicines Agency itself acknowledges.

On the next slide, we can see which regulations apply to these RNA vaccines. They are obviously subject to the control of new vaccines by regulatory agencies. So like all vaccines, like all human products, we have to demonstrate the purity and quality of the raw material. For this, I must refer you to the presentation by Maria Gutschi, who is currently analyzing the European Medicines Agency's report on product purity and quality. In the case of a new formulation, which is the case here, with both a new excipient and a new product, pharmacokinetic studies—meaning biodistribution in the body—are normally required for new vaccines.

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We can see that they've only been partially done. Toxicological study of the new additive must also be carried out. These studies have been very incomplete. And so above all, I'm going to emphasize pharmacokinetics. In other words, this concerns vaccine absorption, distribution and biotransformation in the body, and possible excretion. And this must be studied for new vaccines.

On the next slide regarding product quality, please refer to Maria Gutschi's presentation. In fact, as I told you, when RNA vaccines came onto the market, there were no specific regulations for RNA vaccines because it was a new product. So in fact, what we can gather from the pre-clinical trial reports is that the regulatory agencies, particularly those of the European Union, adapted the regulations. They asked for specific controls—which were inspired, in fact, by the controls for gene therapy products—to be applied to these RNA products.

And so one control for gene therapy products requires genetic identity: that is, the exact nucleotide sequence of the product. This has not been provided. There is a requirement to study the interaction of the nucleic acid with the vector. This was not provided. In fact, stability studies were underway when the vaccine was approved. There is a very technical

condition that must be demonstrated: the presence or absence of CpG dinucleotides. This has not been provided. This is always the requirement for gene therapy products, I remind you—to which RNA vaccines are not officially subject, even though they are, in fact, gene therapy products. For these gene therapy products, research and quantification of product-related impurities is required. So it's very technical: sequences that have been deleted, rearranged, hybridized, oxidized, or depolymerized. This was not provided in the preclinical trials. The presence of antibiotic resistance genes found on the RNA vaccines must also be justified. This hasn't been done either.

For the next slide, I'd like to talk about another point that has come to our attention very recently. Independent researchers, several independent teams, have found the promoter of the SV40 oncogenic virus in the DNA matrix used to synthesize RNA. And this promoter is known to amplify translation into proteins and to facilitate integration into the genome. This is a worrying problem, since DNA contaminants have also been found in vaccine vials. So these vials contain this promoter, which could facilitate the integration of DNA and/or RNA into the genome.

On the next slide, I'd like to remind you of the controls that were thus avoided for these RNA vaccines, as they were not subject to the same controls as gene therapy products. So for example, the route of administration. We have to study the route of administration, study the worst-case scenario. For example, we know that for these vaccines, there was no requirement to aspirate once the needle was inserted into the muscle. Aspiration before injection ensures that the needle is not in a capillary, a blood vessel. If you don't do this, it's possible that you're injecting into a blood vessel. And for gene therapy products, study is required to verify what happens when the most unfavourable route is used, and this has not been done.

What hasn't been done either is biodistribution [study]. We'll talk about that on the next slide. Biodistribution in the human body is very important, as you'll see. The characterization of the presumed mode of action has not been given. In fact, the European Medicines Agency has pointed this out: The mode of action has not been described. As I said earlier, it was difficult to determine the optimal dose, since phase I was conducted at the same time as phase II and III. In terms of potential toxicity targets, it was not specifically determined as to where it could be toxic in the body. Research was not conducted regarding integration in the genome. The European Medicines Agency requires that this be looked into for gene therapy products, even when such integration is unlikely, which is the case for RNA vaccines, but it must still be investigated. Transmission in the germ line has not been researched either, even though there are signals in the gonads, both the ovaries and the testes. It is known that the vaccine goes there, but it has not been investigated.

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There is also a need to carry out sperm fractionation studies and integration analyses. This has not been done. There is also a need to investigate the toxicity of structurally modified proteins; that is, it is possible that the vaccine may cause a vaccinated individual to synthesize proteins other than those investigated. This has not been researched. For gene therapy products, it is also required to study toxicity on embryo-fetal reproduction and therefore go as far as human trials. There should also be study into repeated toxicity, since vaccine manufacturers initially thought there would only be two doses, but in the end, they went as far as five/six successive doses for certain populations, and the toxicity of five or six doses has not been studied.

On the next slide, I focus on the biodistribution and excretion of messenger RNA and the RNA product, in other words, the spike. As I showed you earlier, I have published a review of the literature. We now know that RNA and the spike are found throughout the body, in all organs, and persist for at least several weeks. For gene therapy products, regulatory agencies require study of this biodistribution, especially if the synthesized protein, the spike, is excreted into the bloodstream, which is indeed the case here. I've provided two references here, but there are others that show that spike is indeed found in the blood.

Regulatory agencies also demand that the duration and expression of the spike be determined by PCR. This has not been done. They also require identification of the target organ and confirmation that the product actually reaches the target organ or tissue. This hasn't been done either. They also ask for the study of excretion into the environment in animal models, and also, eventually, for excretion studies for humans. This has not been done. For gene therapy products, they also ask for excretion via semen. This has not been studied.

The next slide presents the continuation of biodistribution problems: the FDA specifically requests that aberrant localization in non-target tissues and cells be studied for gene therapy products. They ask for a determination of exactly how many copies of the vector are present in the cells. This has not been done. They ask for study into the potential horizontal transmission from the patient to family members. This request is made exclusively for viral vectors, but as we are dealing with RNA—which is not a viral vector—and spikes which are known to be distributed throughout the body, these excretion studies should also have been carried out. The FDA also asks for a study of transplacental passage and in breast milk, as well as toxicological study based on the duration of persistence of the product in the animal model. This has not been done.

So just a word— I think I'll speed things up a little because, on the next slide, I'm going to take too much time. Recently, there was an article published on the problem of nanoparticle regulations as well. They are asking for toxicity and biodistribution studies on the complete particle injected: in other words, the lipid nanoparticle with the vaccine RNA inside. This has not been done. It's been done with related products or separate ingredients but it hasn't been done on animals. The actual biodistribution of the vaccine as injected into humans has not been studied.

Next slide: so if messenger RNAs had been classified as gene therapy products, they would have had to undergo all these controls, and then the ambiguity would have been removed. The biodistribution study should have been carried out on the actual particle injected, and not on products of that particle or similar products.

On the next slide, I'd like to emphasize two points. Since we now know from preclinical studies carried out before these RNA vaccines that when lipid nanoparticles equivalent to those in RNA vaccines reach the liver—which is the case and has been verified for COVID RNA vaccines—well, they are able to pass the placental barrier and be delivered to the fetus, and express the gene encoded by the RNA.

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If a woman is vaccinated while she is pregnant, it is possible that the vaccine passes the transplacental barrier. This should have been studied if the vaccine had been classified as a gene therapy product. Moreover, in a declassified FDA document on adverse reactions, it talks about exposure of babies through breastfeeding and of fetuses through the transplacental route. The FDA does not deny this but confirms that it is possible.

In the next slide, we're going to talk specifically about the passage of RNA vaccine into breast milk, which should have been studied if these vaccines had been classified as gene therapy products, which was not done. There are now four independent studies showing that it is possible that the vaccine RNA in a woman injected while breast-feeding her baby can pass into breast milk for at least the first week following injection. This has been proven.

And in fact, on the next slide, in the adverse reactions reported in the first two months after the vaccines were marketed, adverse reactions were noted in breast-fed babies within seven days of vaccination, which corresponds exactly to what was found in the passage of the vaccine into the milk. Moreover, in a response to a citizen's petition, the FDA does not question the detection of RNA in milk. It acknowledges the absence of functional studies demonstrating whether the vaccine RNA detected is translationally active, which should have been studied. And so it would have been very prudent to require RNA excretion studies in milk before commercial release and, above all, before approval was given to inject it into breast-feeding women.

On the next slide, I'd like to remind you that genotoxicity and immune suppression studies are necessary for gene therapy products. But either they haven't been carried out for immune suppression, immunotolerance, or they have been only partially carried out for genotoxicity since they were only done in vitro—that is, on cultured cells. And, in fact, they were carried out with messenger RNAs coding for proteins other than the spike, meaning not actually with the vaccine products. There are no studies of carcinogenicity, mutational insertion, or tumorigenicity in vivo, which are required for gene therapy products. And there are no studies on immunotolerance and immunosuppression, which have now been proven, as I've put here, by two publications that appeared after commercial release.

And on the next slide, I show you that the FDA requires long-term follow-up for gene therapy products, long-term follow-up of adverse effects over five to fifteen years, and this long-term follow-up does not apply to vaccines. So RNA vaccines escape this long-term monitoring because they are not considered gene therapy products. For gene therapy products in particular, they require long-term monitoring of cancers, new neurological diseases, autoimmune diseases, new hematological diseases, and infections. It should be noted that all these diseases are reported after RNA vaccines in peer-reviewed scientific publications. So this should have been studied before commercial release.

And finally, the next slide: RNA vaccines have escaped all these checks on gene therapy products, which are, however, essential for a new formulation and a new principle of action. So why did the European Medicines Agency give emergency approval when specific obligations in the requirements were not met? Why didn't the FDA actually evaluate these vaccines, unlike the European Medicines Agency? We know that in 2021, senior FDA officials resigned because they felt excluded from key vaccine decisions. All the references for this are in the preprint I pointed out. And according to documents leaked from the European Medicines Agency, it was learned that in late 2020, U.S. and E.U. government officials pressured European authorities to quickly approve the vaccine, despite safety concerns.

And so in conclusion, on the next slide, I'd like to ask that in future, we consider whether or not all messenger RNA products should be subject to the same regulations and controls, whether or not they are considered vaccines against infectious diseases.

[00:45:00]

There is no justification for subjecting therapeutic RNAs to strict controls when they are intended for patients who ultimately represent a small proportion of the world's population—because people with genetic defects or cancers are numerous, obviously too numerous, but they represent a small proportion of the population—whereas RNA vaccines are intended for the vast majority of the world's population, and a healthy one at that. Why exclude them from such regulation? That's the question I'm asking; and I think everyone should understand that it's very important, even though it's a rather onerous subject.

That's it, I'm done. Thank you for your attention. I hope I haven't taken too long.

Konstantinos Merakos
Yes, excellent. Thank you, Madame Banoun; thank you very much. We'll now go to our commissioners for questions. Please, go ahead.

Commissioner Massie
Hello, Madame Banoun, and thank you very much for this very exhaustive overview of the historical development of these products, which were made available to the public very quickly. My first question concerns your analysis, which to me looks like a literature review or a review of available government documents. And you have the expertise as a researcher that enables you to do this kind of reading and ask the related questions, and then try to find the documents that will make it possible to document the whole narrative you've presented to us.

My question for you is this: You know the research community—you have other colleagues in France and abroad. How many researchers would have this kind of expertise and could have done an analysis somewhat similar to the one you've presented to us? Does what you've done require such unique expertise that only a few people in the field can do it?

Hélène Banoun
No, I don't think so because I haven't been an expert in vaccines or regulations for very long. I looked into the problem because I thought it was important. In fact, I've already submitted my preprint twice to international journals. It was probably rejected because there were some inaccuracies as I'm not an expert. So what I'm giving you here is the result of the corrections I made following the comments of the experts who judged me. They're anonymous experts, but I'm guessing they must be part of official regulatory bodies. So I've been working on it; it just takes a lot of time and precision, but it's not that complicated. You need to attend to it, but I think this problem can't elude scientists, especially those who are regulatory experts. Besides, all those who criticized my preprint said that I was right to pose this problem, that it was a real problem: this problem of contradictory regulation between vaccines and gene therapy products. So I think it's within the grasp of a lot of people.

Commissioner Massie
My next question concerns the quality of these products. We've had other experts come and testify before the Commission, and they've raised a whole series of problems similar to those you mentioned in terms of product quality. Maria Gutschi was here and other experts also made presentations. And when we analyze all the questions raised about product

quality—and above all, the fact that when we go into clinical trials, certainly in phase II, we should have products of absolutely impeccable quality, so that the conclusions we draw about product efficacy, and eventually safety, cannot be called into question given the heterogeneity of product quality. This poses a problem for the conclusions of clinical trials.

And here's the question: Given that we've rushed through a lot of stages—in both evaluation and production, in manufacturing—based on the analyses you've carried out, do you think that we currently have technologies that are sufficiently robust to ensure the large-scale commercial production of these products to the right manufacturing standards? To ensure that the product, once marketed, will really have all the attributes we're looking for from the regulatory bodies?

[00:50:00]

Hélène Banoun
So there are two ways of answering. There's the way Maria Gutschi answered your question, by analyzing the reports of the European Medicines Agency, which itself specifies that there is product heterogeneity. And then there's the clinical result we've been observing, since a study recently appeared—I believe from Denmark—which points out something we've been noticing for a long time but which hadn't been officially published in a peer-reviewed journal: that is, there's great heterogeneity in batch toxicity. Since some batches are highly toxic, they have led to many reports of adverse events; and for some other batches, there are very few. So in fact, what was noted in the analysis of product quality, namely product heterogeneity, is found in the clinical effects. In other words, we find heterogeneity in batch toxicity. Therefore, it seems that the manufacturing process is poorly controlled.

Commissioner Massie
And from your experience examining other biological products—for example, therapeutic antibodies that are widely used in cancer therapy—do the technologies that lead to the production of these commercial products have the same kind of problems—in terms of the heterogeneity or quality—as the products that are available on the market?

Hélène Banoun
Well, I can't answer that because I haven't studied these products. I don't know if Maria Gutschi has. Well, I'm sorry, but I can't give you an answer.

Commissioner Massie
Okay, thank you. Do my colleagues have any questions for Madame Banoun? Do you have any questions? No?

Konstantinos Merakos
Madame Banoun, the National Citizens Inquiry would like to thank you most sincerely for your valuable information, and for your very educational PowerPoint. So we thank you very much and wish you, since you're in France, a good afternoon or good evening.

Hélène Banoun
Well, thank you for inviting me. And I'd just like to add a few words. I think it's very important to tackle this problem of regulation and to try to make it understood to lawyers and politicians because it's the politicians who ultimately decide on official regulations. I think it's very important to make everyone—scientists, lawyers, and politicians—understand that messenger RNAs are gene therapy products and must undergo all the controls required for gene therapy products. This is important for the future because there is now talk of generalizing this technology to other vaccines. This is already underway, with plans to build factories.

So where are we going with this technology? This is very important and we must quickly address the problem. The time to do it is now. Thank you very much.

Konstantinos Merakos
Excellent. Thank you once again.

[00:53:18]

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The evidence offered in this transcript is a true and faithful record of witness testimony given during the National Citizens Inquiry (NCI) hearings. The transcript was prepared by members of a team of volunteers using an "intelligent verbatim" transcription method, and further translated from the original French.

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